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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/825,482 | 04/03/2001 | Menashi A. Cohenford | CYM-035US | 2116 |
| 23639 | 7590 | 08/07/2003 | | |
| BINGHAM, MCCUTCHEN LLP THREE EMBARCADERO, SUITE 1800 SAN FRANCISCO, CA 94111-4067 | | | EXAMINER | SIEW, JEFFREY |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1637 | 13 |
| DATE MAILED: 08/07/2003 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application N . | Applicant(s) |
| | 09/825,482 | COHENFORD ET AL. |
| | Examiner | Art Unit |
| | Jeffrey Siew | 1637 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4,6-16 and 38-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4,6-13,15,16,38-46,48 and 49 is/are rejected.
- 7) Claim(s) 4,9-14,38,42-47 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 03 April 2001 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. The amendment filed 7/22/03 has been entered. However upon further evaluation of the submitted prior art, the finality of the previous office action is withdrawn and a new non final office action follows. Pending claims to be examined are 1-4, 6-16, 38-49.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 4,9-14 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 38,42-47. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- A) Claim 6 depends on cancelled claim 5. It is unclear the metes and bounds of claim 6.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,2,6-8 & 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steinman (US5,849,497 Dec. 15, 1998) in view of Orum et al (NAR vol. 21 No. 23 pp. 5332-5336 1993).

Steinman teach a method of detection of selected stain of an organisms comprising providing a sample that may comprise at least one selected and non selected strain, providing a plurality of primers complementary to regions of selected and non selected strain, exposing to at least one probe that is complementary to non selected strain in between primers and probe is nucleic acid analog, amplifying and detecting (see whole doc. esp. abstract & col.2 lines 4-55 & col. 1 line 40& 42). They teach a probe greater than 8 nucleotides (see Table I). They teach separation and detection by gel electrophoresis (see col. 10 lines 4-6).

Steinman do not teach PNA probe to block PCR.

Orum et al teach the use of PNA probe to block and selectively amplify PCR target sequences (see whole doc. esp. abstract).

One of ordinary skill in the art would have been motivated to apply Orum et al's PNA probes to Steinman et al's method of differentiating strains in order to selectively amplify target sequence. Orum et al states that PNA have higher thermal stability and specificity and effectively block formation of PCR product to selectively amplify/suppress target sequences (see abstract). It would have been *prima facie* obvious to apply Orum et al's PNA probes to Steinman et al's species amplification

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4. Claims 3,4,9-12, 38-45 & 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steinman (US5,849,497 Dec. 15, 1998) and Orum et al in view of Lancaster et al (US5,863,717 Jan. 26, 1999).

The teachings and suggestions of Orum et al and Steinman are described previously.

Steinman do not teach HPV.

Lancaster et al teach PCR amplification of HPV(see whole document). They teach low risk strains HPV 6 & 11 and high risk HPV 16 & 18 (see col. 1 line 26 & 27). They teach the association with pathogenesis of cancer (see col. 1 lines 5-10). They teach the target regions E1, E2, L2 and L1 (see Figure 2A).

One of ordinary skill in the art at the time the invention was made would have been motivated to apply Lancaster et al's primers to Steinman method of PCR in order to detect different strains of HPV. Lancaster et al teach that HPV infection has high correlation with cervical cancer. It would have been prima facie obvious to combine Steinman method of strain differentiation with Lancaster et al's primers in order to detect the high risk strains HPV in patients.

5. Claims 13, 15,46 & 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steinman (US5,849,497 Dec. 15, 1998) and Orum et al in view of Mahoney et al (US6,045,993 April 4, 2000)

The teachings and suggestions of Orum et al and Steinman are described previously.

Steinman do not teach SEQ ID NO:10 and 11 or cervical scrapings.

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Mahoney et al teach PCR amplification with primers(see whole doc. esp. abstract). They teach primer of SEQ ID NO:1 which matches claimed SEQ ID NO:11. They teach primer SEQ ID NO:2 which matches claimed SEQ ID NO:10. They teach cervical specimens such as swabs and brushings, scrapings (see col.2 line 34).

One of ordinary skill in the art at the time the invention was made would have been motivated to apply Mahoney et al's primers to Steinman method of detection in order to amplify HPV in sample. Mahoney teach the successful amplification with SEQ IDNO:1 & 2 (see example 1). It would have been prima facie obvious to apply Mahoney et al's teachings of primers to Steinman in order to successfully amplify HPV for detection.

SUMMARY

6. Claims 14 & 47 are objected for depending on rejected claim and under double patenting. There is no prior art that teach or suggest SEQ ID NO:6 or 7. The closest prior art is Bauer et al who teach SEQ ID NO:21 which is 25 base pairs and used in probing HPV but Bauer et al explicitly state longer probes lead to less mismatches and give preferably sizes of 18-20 bases (see col. 9 lines 5-15).

CONCLUSION

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and FAX (703)-308-4242.

Jeffrey Siew
JEFFREY SIEW
PRIMARY EXAMINER

August 6, 2003